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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 09/463,890 | 04/28/2000 | ULRICH H. KOSZINOWSKI | 203640 | 6925 |
| 23460 | 7590 | 10/30/2006 | EXAMINER | |
| LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6780 | | | SULLIVAN, DANIEL M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1636 | |

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/463,890 | KOSZINOWSKI ET AL. | |
| | Examiner | Art Unit | |
| | Daniel M. Sullivan | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 August 2006.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 36,37,40-70,73 and 74 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 36,37,40-43,45-64,67-70,73 and 74 is/are rejected.

7) Claim(s) 44,65 and 66 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 22 August 2006 in response to the Advisory Action mailed 5 July 2006. Claims 36, 37, 40-48 and 50-70 were considered in the 5 July Advisory Action. Claims 36, 37, 40-57, 63, 64 and 67-69 were amended and claims 73 and 74 were added in the 22 August Paper. Claims 36, 37, 40-70, 73 and 74 are pending and under consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 August 2006 has been entered.

Response to Amendment and Arguments

Priority

The Advisory Action indicated that the claims presented after final were not entitled to benefit of the foreign priority application because the priority application does not provide descriptive support for the claimed subject matter. In response, Applicant has amended independent claim 36 such that the claims are now directed to a bacterial artificial chromosome containing bacterial nucleic acid sequences and an infectious herpes virus genomic sequence

lager than 100kb wherein the BAC enables replication of the infectious herpes virus genomic sequence in a host cell.

In the remarks filed with the 22 August Paper, Applicant contends that support for the claims is found in the English translation of the German patent application at p. 3, ll. 8-11; p. 3, l. 34 through p. 4, l. 33; p. 5, ll. 11-17; and Figure 1. However, as stated in the 5 July Advisory Action, “The foreign application must be examined for the question of sufficiency of the disclosure under 35 U.S.C. §112...” (P. 3, ¶2; quoting MPEP 201.15.)

The claims are now generic to a bacterial artificial chromosome containing any bacterial sequence and limited to comprising an infectious herpes virus genomic sequence larger than 100 kb. The portion of the priority document describing BACs comprising infectious virus genomic sequences teaches, “Suitable cloning vehicles are low-copy vectors, since the stability of the cloned DNA is only ensured by the low number of copies of the plasmids.” Thus, the priority document teaches that practicing the invention using BACs comprising bacterial sequences other than low-copy vectors was unpredictable at the time the priority application was filed. This unpredictability was also recognized in the art as evidenced by the teachings of Warnes et al. (1986) *Plasmid* 16:116-123. Warnes et al. teaches that plasmids comprising as little as 21 kb of CMV genomic DNA were unstable under all of the growth conditions used therein. (See especially the ¶ bridging pp. 118-119, Figure 3 and the caption thereto.) Warnes et al. further teaches that the reason for the plasmid instability is that the large DNA places an unacceptable metabolic load on the cell. (See especially p. 122, col. 2, ¶1.) In view of these teachings, the skilled artisan would reasonably expect that the metabolic load, and hence the plasmid instability, would increase as plasmid size increases. Therefore, the skilled artisan would expect

that making a viable vector comprising an insert of 100 kb or greater would be highly unpredictable.

The priority application provides no guidance with regard to making viable BACs comprising large inserts and any bacterial nucleic acid sequence other than a low copy vector and, as discussed above, the specification of the priority document teaches that low copy is required to insure stability of the vector. Likewise, the art teaches that vectors comprising large segments of CMV DNA are unstable. In view of the unpredictability of the art and the failure of the priority application to teach how to make a BAC comprising bacterial DNA other than a low copy vector, the skilled artisan would have to engage in undue experimentation to make a BAC comprising any bacterial nucleic acid sequence other than a low copy vector and an infectious herpes virus genomic sequence larger than 100 kb. Thus, the priority application is not enabling for the broad scope of what is presently claimed in accordance with the requirements of 35 USC §112, first paragraph. Therefore, the claims are not entitled to benefit of the German priority application.

Sequence Compliance

Perfection of the submission filed 1 September 2005 in accordance with the requirements of 37 CFR 1.821 through 1.825 by the statement directing entry of the paper copy of the sequence listing into the specification (22 August Paper, p. 7, ¶2) is acknowledged.

Art Unit: 1636

Claim Rejections - 35 USC § 102 & 103

Claims 36, 37, 40-43, 45-52, 53-55, 56-64 and 67-70 **stand rejected** under 35 U.S.C. 102(a) as being anticipated by Messerle et al (PNAS USA, December 1997, Vol. 9, pages 14759-14763; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 6 and herein below.

Claims 36, 48, 51, 54, 57-60, 63-64 and 67-69 **stand rejected** under 35 U.S.C. 102(e) as being anticipated by Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998; see the entire patent) for the reasons set forth in the 3 March Office Action commencing at page 7 and herein below.

Claims 36, 43, 48, 51, 54, 57-60 & 63 **stand rejected** under 35 U.S.C. 102(a) as being anticipated by Delecluse et al (Proceedings of the National Academy of Sciences, USA. 7 July 1998, Vol. 95, pages 8245-8250; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 9 and herein below.

Claims 37 and 40-43 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998; see the entire patent) in view of Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p.B8, 1996; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 12 and herein below.

Response to Amendment and Arguments

Applicant sought to overcome the rejection by amending the claims to comport with the disclosure of the priority application. However, as described herein above, in view of the unpredictability of the art and the failure of the priority application to teach how to make a BAC comprising bacterial DNA other than a low copy vector, the skilled artisan would have to engage in undue experimentation to make a BAC comprising any bacterial nucleic acid sequence other than a low copy vector and an infectious herpes virus genomic sequence larger than 100 kb. Therefore, the priority application is not enabling for the broad scope of what is presently claimed in accordance with the requirements of 35 USC §112, first paragraph.

In view of the foregoing, the skilled artisan would conclude that the priority application does not provide an enabling disclosure of the subject matter presently claimed sufficient to meet the requirements of 35 USC §112, first paragraph. Therefore, the claims are not entitled to benefit of the priority application.

New Grounds

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 73 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p.B8, 1996; previously made of record).

The claims are directed to an isolated our purified infectious herpes virus genomic sequence produced by the method of claim 67 wherein the viral genomic sequence comprises a sequence larger than 200 kb.

Messerle et al teach the construction of two BAC/MCMV hybrids wherein the hybrid vectors comprise BAC sequences and an infectious viral genomic sequence of >200kb (i.e. 235 kb minus ~15 kb), and further teaches that the constructs were used to produce MCMV virions (i.e. due to complementation between the two vectors upon co-transformation in eukaryotic host cells). Absent evidence to the contrary, the mutagenized infectious herpes virus genomic sequences comprised by the MCMV virions are the same as the infectious herpes virus genomic sequence of the instant claims 73 and 74.

Allowable Subject Matter

Claims 44, 65 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Art Unit: 1636

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Daniel M. Sullivan, Ph.D.
Primary Examiner
Art Unit 1636